

Application No. 10/786,725
Paper Dated: June 25, 2010
In Reply to USPTO Correspondence of April 26, 2010
Attorney Docket No. 3896-031736 (P-6004)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application No. : 10/786,725 Confirmation No. 2750
Appellants : KIRK D. SWENSON et al.
Filed : February 25, 2004
Title : SAFETY BLOOD COLLECTION HOLDER
Group Art Unit : 3736
Examiner : Rene T. Towa
Customer No. : 32182

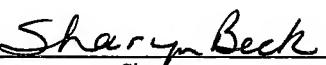
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REPLY BRIEF TO EXAMINER'S ANSWER

PURSUANT TO 37 CFR §41.41(a)

Sir:

The present paper represents a Reply Brief in response to the Examiner's Answer mailed on April 26, 2010 for the above-identified Appeal, a response to which is due by June 26, 2010. The Board is respectfully requested to consider this Reply Brief directed to new points of argument raised in the Examiner's Answer.

I hereby certify that this correspondence is being electronically submitted to the United States Patent and Trademark Office on June 25, 2010.	
06/25/2010	
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Sharyn Beck	
Typed Name of Person Signing Certificate	

(A) The Examiner asserts that the combination of Hollister ('311) with Hollister ('842) is proper and renders the claimed invention obvious.

In response to Appellants' arguments, set forth on pages 12-15 of the Appeal Brief, the Examiner has now relied upon an entirely new basis for arguing that the combination of Hollister ('311) with Hollister ('842) is obvious. Appellants have responded to this new reasoning as set forth below.

I. The Examiner's arguments are based on an entirely new reasoning than the rejection in the final Office Action and the rejection in the Examiner's Answer.

In the final Office Action and on page 5 of the Examiner's Answer, the Examiner states that in regard to claim 1, since Hollister ('842) teaches a holder assembly wherein the addition of an annular skirt 76 allows an annular protrusion 18 on a collar 2 to externally mate with a holder housing 72, it would have been obvious to one of ordinary skill in the art at the time Appellants' invention was made to provide the holder assembly of Hollister ('311) with an annular skirt such that the collar is received between the annular skirt and the receiving port of the holder housing as taught by Hollister ('842) *in order to allow an annular protrusion on the collar to externally mate with a holder housing* (emphasis added).

In response to this rejection, Appellants asserted on pages 11-12 of the Appeal Brief filed February 1, 2010 that the combination of Hollister ('311) with Hollister ('842) fails to provide any suggestion to: (A) provide an annular skirt on Hollister ('311); (B) locate a mounting collar between an annular skirt and a needle receiving portion of the holder housing; and (C) redesign the relationship between the mounting collar and the holder housing to form an interfitting relationship of the collar with the annular skirt such that the shield can pivot with respect to the collar and the annular skirt. Although claim 1 does not specifically call for an "interfitting relationship" between the collar and the annular skirt, the Examiner's obviousness conclusion statement requires this interfitting relationship *in order to allow an annular protrusion on the collar to externally mate with a holder housing*. In other words, in order to allow an annular protrusion on the collar to *externally mate with a holder housing*, as suggested by the Examiner, the relationship between the mounting collar

and the holder housing in Hollister ('311) must be redesigned, which, absent hindsight reasoning, would not be obvious to one having ordinary skill in the art.

In response to Appellants' arguments set forth on pages 12-15 of the Appeal Brief, the Examiner has now relied upon an entirely new basis for arguing that the combination of Hollister ('311) with Hollister ('842) is obvious.

On page 13 of the Examiner's Answer, the Examiner now argues that Hollister ('842) teaches that it is known to mate a collar 6, having a base 2 and a section 2B (note that previously, the Examiner referred to element 2 as being the "collar" in Hollister) to a housing 60 without an annular skirt via a "male luer" or housing end 62 (*see* Fig. 3) or alternately to attach the collar 6 to a housing 72 with the addition of an annular skirt 76 via a "male luer" or housing end 74 (*see* Fig. 4). Previously, the Examiner relied upon the Fig. 4 embodiment of Hollister ('842), directed to a luer lock type syringe in combination with Hollister ('311) to support the obviousness rejection. Now, the Examiner is relying on the Fig. 3 embodiment, which is directed to a luer slip type syringe, and the luer lock type syringe of Fig. 4, to assert that a skirt, such as shown in the luer lock type device, is an "alternate" securing means. It is noted that Appellants are unable to locate any conclusion statement in the Examiner's Answer as to why one would be motivated to use the "alternate" skirt securing means in the Hollister device. However, *even if* the teachings of Hollister ('842) using both a slip luer type device and a luer lock type syringe *would* motivate one having ordinary skill in the art to modify Hollister ('311) to include this "alternate" skirt securing means, one would still not arrive at the present invention as the skirt taught by Hollister ('842) teaches *threads* (78) along which the extension (18) moves in an axial direction with respect to the syringe. The incorporation of this type of skirt in Hollister ('311) would necessarily result in axial movement of the collar and shield along the axis of the holder housing and eventually result in the disengagement of the shield and collar from the holder housing.

II. The Examiner's arguments are based on a mischaracterization of the Hollister ('842) reference.

The Examiner asserts that Hollister ('842) also teaches that when adding an annular skirt 76, a securing means, (in this case in the form of threads 78 on the annular skirt 76 and a protrusion 18 on the collar 6) may be added to secure the collar 6 to the housing 72

even though the mating means 9 (in this case a slip-fit) of the housing end 74 to the collar 6 remains the same and unchanged (*i.e.*, slip-fittedly mated).

Appellants respectfully disagree with the Examiner's position as a slip luer type syringe and a luer lock type syringe are very different devices. In a slip luer type syringe, a specific tapered arrangement is provided between the syringe barrel and the collar to hold the collar in place on the syringe barrel. In a luer lock type syringe, this specific tapered arrangement is not necessary because the collar is fixedly engaged with a skirt extending from the syringe barrel. The statement in Hollister ('842) that the male luer 74 (in the Fig. 4 embodiment) will remain "slip-fittedly mated" with section 2b, if the safety adapter shown in Fig. 2A is used, simply means that the male luer 74 fits into and contacts the base 2 when the circumferential extension 18 engages the threads of the threaded collar or skirt 76. The rotation of the collar and shield of Hollister ('842) away from the syringe barrel would result in axial movement of the collar and shield with respect to the syringe barrel and disengagement of any "slip-fit" of the collar from the male luer (76). Further still, as stated above, *even if* one would be motivated to include a skirt in Hollister ('311), the incorporation of the Hollister ('842) skirt in Hollister ('311) would necessarily result in axial movement of the collar and shield along the axis of the holder housing, eventually resulting in the disengagement of the shield and collar from the holder housing. This modification would destroy the functioning of the Hollister ('311) device which calls for rotation of the collar and shield about the holder housing without any axial movement of the collar and shield with respect to the holder housing.

III. Examiner's statement that Hollister ('311) includes a groove and boss mechanism which is an improvement over threaded mechanisms is a misleading statement.

On page 16 of the Examiner's Answer, the Examiner states that one of ordinary skill in the art armed with both Hollister ('311) and Hollister ('842) would necessarily improve the securing means between the collar 18 of Hollister ('311) and a presumably added annular skirt as suggested by Hollister ('842) to include a groove/boss mechanism as taught by Hollister ('311) in order to keep the trumpeted improvement offered by the rotatable characteristics of the device of Hollister ('311). The Examiner then asserts that "doing otherwise (*i.e.*, using a securing means that does not allow a rotatable connection)

may go against the principle of operation of Hollister ('311)". This statement **affirms** Appellants' position that using the threaded skirt connection of Hollister ('842) in the Hollister ('311) device would destroy the functioning of the Hollister ('311) device.

However, then the Examiner provides the following misleading statement: "Hollister ('311) touts the groove and boss mechanism of its device as an improvement over the prior art, which uses threaded mechanisms that may end up in any orientation and would thus prevent the phlebotomist from viewing the true angle of the cannula (*see* column 1, lines 45-68; column 2, lines 1-11)". This statement as used in the Examiner's Answer implies that the non-axially movable connection taught by Hollister ('311) is an improvement over previously used threaded, axially movable connections of a collar and shield to the holder. In actuality, this statement is in reference to a needle assembly itself which is threaded into the safety device. When the needle assembly is threaded into the safety device, it may end up in any orientation and, as such, the safety housing attached to the device would sometimes get in the way and prevent the phlebotomist from viewing the true angle of the cannula (*see* column 1, lines 55-60).

Accordingly, it is Appellants' position that one having ordinary skill in the art would not be motivated to: (1) place the Hollister ('842) skirt on the Hollister ('311) device; (2) redesign the relationship of the annular protrusion on the collar such that it externally mates with the skirt and allows for rotation about the needle; and (3) physically change the thread design on this skirt such that as the redesigned boss/collar arrangement interacts with the threads, this interaction occurs in a manner which precludes any axial movement of the collar with respect to the holder.

In response to Appellants' arguments set forth on pages 12-15 of the Appeal Brief, the Examiner has now relied upon an entirely new basis for arguing that the combination of Hollister ('311) with Hollister ('842) is obvious.

IV. Examiner's argument that Hollister ('842) "does not criticize, discredit or otherwise discourage" the use of a groove and boss mechanism for radial rotation is not understood.

The Examiner asserts that Appellants have failed to provide any evidence that Hollister ('842) teaches away from any type of radial rotation during use due to the possibility of leakage occurring between the luer interface of male luer 74 and section 2b,

thus rendering the device inoperable. From this statement, the Examiner then asserts that Hollister ('842) "does not criticize, discredit or otherwise discourage" the use of a groove and boss mechanism for radial rotation. Appellants disagree. One having ordinary skill in the art understands how a luer lock system operates and, through an ordinary viewing of the threads on the skirt in Hollister, would recognize that radial rotation of the collar during use would result in disengagement of the collar from the luer. Accordingly, leakage will occur. Hollister ('842) does not necessarily have to "criticize" or "discourage" against radial rotation when one having ordinary skill in the art would recognize that such leakage will occur if one unscrews the collar in a luer lock system.

V. Examiner's requirement for an affidavit and/or declaration is not necessary to support a known operating feature in Hollister ('842).

Throughout the prosecution history of the application, Appellants have argued that radial rotation of the luer lock device of Hollister ('842) would render the device inoperable as it would lead to leakage occurring between the luer interface of the male luer 74 and section 2b. On page 20 of the Examiner's Answer, the Examiner now asserts that this argument is "unsubstantiated in the absence of a timely-provided valid affidavit and/or declaration". Appellants disagree. First of all, it is noted that such an affidavit or declaration has not been required prior to this point in the prosecution even though the functioning of a luer lock device has been previously argued (*see* Appellants' response dated November 5, 2008). Secondly, the requirement of an affidavit or declaration describing how a luer lock device functions is not necessary if such functioning of the device is well known to one having ordinary skill in the art. Accordingly, for the reasons set forth above, the combination of Hollister ('311) with Hollister ('842) fails to render claims 1, 2, and 9 obvious.

(B)-(D) The Examiner's Answer fails to provide any additional arguments to rebut Appellants' position with respect to dependent claims 3-6.

Dependent claims 5-6 are specifically directed to the outer surface of the collar including a protrusion and an inner surface of the annular skirt including a groove adapted to receive the protrusion on the annular collar to provide an interface fit when the collar is received between the annular skirt and the needle receiving port of the holder housing. The Examiner's arguments are the same as those provided with respect to claim 1. These

arguments have been addressed above. Accordingly, for the reasons provided, the combination of Hollister ('311) with Hollister ('842) and further in view of either Kobayashi or Newby, fails to render claims 3-6 obvious.

(E)-(F) The Examiner's Answer fails to address the arguments with respect to claim 7 as set forth in the Appeal Brief.

Claim 7 calls for the annular skirt on the holder housing to substantially enclose an open end of the hook arm, thereby preventing the interface fit between the hanger bar and the hook arm from releasing when the collar is received between the annular skirt and the needle receiving port of the holder housing.

The Examiner relies on the teachings of Alesi as teaching that it is known to provide a living hinge attached to an annular skirt of a holder housing, and then relies on Newby and/or Kobayashi as teaching that it is known to provide holder assemblies with a hinge comprising a hook arm attached to a collar and that hanger bar/hook assemblies are art recognized substitutes for living hinges. However, as argued in the Appeal Brief (sections (E) and (F), pages 18-20), none of the cited references disclose or suggest an annular skirt that encloses an open end of a hook arm preventing the release of the interface fit between the hanger bar and hook arm as recited in the claim. Alesi does not even enclose the living hinge and, as such, one would not be motivated to position this "annular skirt 8" in the needle holding device of Hollister ('311) as modified by Hollister ('842) and further modified by Newby or Kobayashi to cooperate with an open end of a hook arm to prevent an interface fit between the hanger bar and the hook arm from releasing when the collar is received between the annular skirt and the needle receiving port of the holder housing. Whether or not it is "known to use a full hinge having holes and pegs to securely attach a housing to a collar", as newly asserted in the Examiner's Answer, does not overcome the deficiencies of the cited references and the lack of showing and/or motivation of the references to teach the claimed invention. For these reasons, the combination of Hollister ('311) with Hollister ('842) in view of either Newby or Kobayashi and further in view of Alesi, fails to render this claim obvious.

(G) Appellants disagree with the Examiner's assertion that the addition of Gyure to the combination of references renders claim 8 obvious.

Claim 8 recites the feature that the collar has one or more slits defined in a rearward annular collar section. The Examiner relies on the "series of slits forming the stepped portions" shown in Figs. 3-4 of the reference in rejecting claim 8. However, as argued in the Appeal Brief, (section G, pages 20-21), these stepped portions are provided **within** the hub or collar, are not "slits", and, as stated at column 4, lines 16-20, are provided to vary the inside diameter of the hub or collar. These step portions are not provided in the rearward annular collar section as slits, as set forth in the claim, to allow for additional flex in the rearward collar section of the collar to enable insertion into the recess of the holder housing with less force. For these reasons, the combination of Hollister ('311) with Hollister ('842) and further in view of Gyure, fails to render this claim obvious.

CONCLUSION

For the reasons set forth above, Appellants believe claims 1-9 are patentable over the cited art and are in condition for allowance. Reversal of all of the Examiner's rejections and allowance of these claims are respectfully requested.

Respectfully submitted,

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